



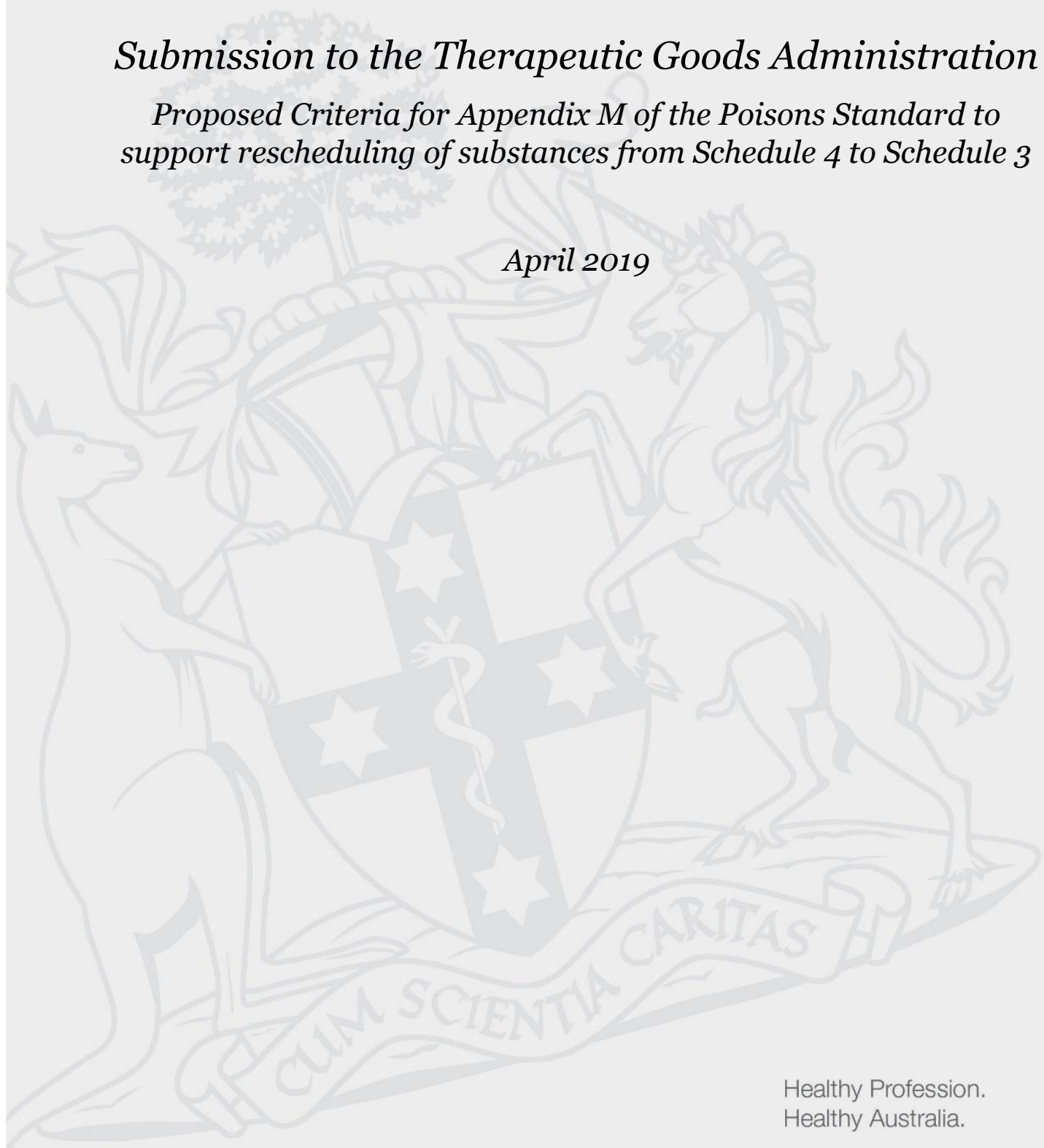
RACGP

Royal Australian College of General Practitioners

Submission to the Therapeutic Goods Administration

Proposed Criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 to Schedule 3

April 2019



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RACGP submission to the Therapeutic Goods Administration

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Key recommendations

Separation between prescriber and dispenser

1. Community pharmacies display clear signage to inform consumers about any material, financial or commercial interest the pharmacy may have with suppliers of Appendix M / Schedule 3 medications.

Public health policies

2. Importance of antimicrobial stewardship must carefully be considered.

Evidence-base, evaluation and professional standards

3. Down-scheduling of medications must be limited to those that are very safe, used to treat minor illnesses, and do not have monitoring needs.
4. Evidence should be presented and publically available to support decisions to down-schedule, and to model for unintended consequences of down-scheduling.
5. An evaluation process for monitoring the impacts of changes to scheduling developed, including the societal costs of overuse and shifts from lifestyle interventions to pharmaceuticals.
6. A full quality assurance program should be developed and implemented at a national level prior to a drug intervention being commenced.
7. Pharmacists should have Appendix M / Schedule 3 prescribing numbers to aid in detection of prescription abuse, through audit trails.
8. Mandatory face-to-face assessment between a pharmacist and a patient, to avoid internet self-dispensing or dispensing to a third party

Compliance

9. Pharmacies dispensing Appendix M / Schedule 3 drugs should be registered with the Therapeutic Goods Administration. As part of this process, pharmacies should be required to declare all commercial (financial and non-financial) arrangements with drug companies regarding Appendix M / Schedule 3 products
10. Applicants (the drug company) should be required to declare how many pharmacies they have commercial (financial and non-financial) arrangements with.

Executive summary

The Royal Australian College of General Practitioners (RACGP) thanks the Therapeutic Goods Administration (TGA) for the opportunity to comment on the consultation document, *Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 to Schedule 3*. We welcome the opportunity to re-think the safety and necessity of pharmacy only medication in both S3 and the proposed Appendix M schedule.

We recognise that external pressures are continually at play to down schedule drugs. These pressures come from a number of sources, including political pressure from comparisons with other countries (albeit with very different health systems), pharmacy, patient advocates, and drug companies. Such pressures often run counter to efforts to ensure good health system stewardship and the quality use of medicines.

The RACGP is concerned that the currently proposed Appendix M poses many risks to our patients and to the healthcare system. The particular areas of concern are:

1. Conflict of interest - pharmacies both advise and supply medicines and there is strong pharmaceutical industry influence within pharmacies.
2. The undermining of existing health policy aimed at promoting antimicrobial stewardship, non-drug interventions, and use of more cost effective medications.
3. Patient safety, which may impacted in a number of areas:
 - the provision of health advice by lesser trained pharmacy assistants,
 - loss of adequate history taking
 - loss of adequate information available for clinicians
 - reliance on checklists.
4. Patient care:
 - may be harmed through increasing fragmentation of care.
 - may be harmed if personalised medical advice is lost because pharmacy staff rely on checklists that don't take account of multi-morbidity and patient preferences
 - may be harmed through the loss of opportunities for prevention and monitoring
 - requires face-to-face consultations to prevent mail-order medication dispensing so quality assurance can occur.
5. Patient convenience:
 - In many instances, convenience could be improved for patients through larger pack sizes.

The Royal Australian College of General Practitioners

The RACGP is Australia's largest medical organisation, representing more than 40,000 members who provide more than 154 million general practice services each year to more than 24 million Australians.

The RACGP's mission is to improve the health and wellbeing of all people in Australia by supporting GPs, general practice registrars and medical students.

The RACGP has a strong interest in clinical governance, and has strong positions on ongoing [antimicrobial stewardship](#), [appropriate prescribing](#) and the over use of medicines. The proposal for Appendix M may run counter to measures to reduce or rationalise the use of many medications.

1. Separation between prescriber and dispenser

The RACGP is concerned by the proposed lack of separation between the prescriber and dispenser, which has potential for serious conflicts of interest that may result in patient harms.

Conflict of interest

The proposed policy does not detail any management of potential conflicts of interest. This issue is particularly concerning where pharmacy staff would be required to issue patient health advice. The RACGP strongly recommends that the Therapeutic Goods Administration consider introducing standards allowing only Registered Professional staff to provide therapeutic advice within a pharmacy and to introduce safeguards against conflicts of interest.

As pharmaceutical industry influence within pharmacies is strong, it is important consumers be advised of instances where the pharmacy has a commercial arrangement with suppliers of therapeutic goods and medicines. The RACGP strongly recommends that community pharmacies should be required to display clear signage to inform consumers about any relevant material, financial or commercial interest the pharmacy may have with suppliers if Appendix M / Schedule 3 medications.

2. Potential impacts on existing public health policies

In the interests of antimicrobial stewardship and the appropriate use of medicines, the RACGP recommends against the down-scheduling of these medicines. The proposed policy has potential to contribute to an increase in the over use, and unnecessary use, of medicines. It also stands to mitigate against existing policies in primary care that target antimicrobial resistance.

The Therapeutic Goods Administration should also consider the likelihood and impact of any advertising of the down-scheduled substance. The following examples highlight issues with Schedule 3 medications for Appendix M listing:

- A 3-day course of trimethoprim for uncomplicated urinary tract infection in women.

This should be prescribed with a high level of diagnostic accuracy to ensure they are not excessively prescribed. The diagnosis of urinary tract infection by clinical criteria alone has been demonstrated to have an error rate of 33%¹.

- The down-scheduling of the use of chloramphenicol for topical treatment of conjunctivitis.

There has been no evaluation or monitoring of the impact of this shift in Australia. However, in the UK a similar down-scheduling led to a 48% increase in use². Sticky sore eyes are commonly caused by viral infections. No treatment results in recovery of 74% of cases³.

3. Monitoring, evaluation, compliance and enforcement of Appendix M

3.1 Evidence

The RACGP seeks clarification on any prior evaluation of medicines that have previously been Schedule 4 and down-scheduled to Schedule 3. Evidence should be presented to support decisions to down-schedule, and to model for unintended consequences of down-scheduling.

The consultation document proposes that evaluation of down-scheduled medicines will be in the remit of state and territories. Regulatory frameworks to ensure patient safety for pharmacy-only medicines are not robust. There needs to be a process to monitor the impacts of changes to scheduling that

considers societal costs of overuse of medications and a shift from lifestyle interventions to pharmaceutical interventions.

3.2 Monitoring and evaluation of Appendix M

Patients and professionals must be confident that appropriate systems are in place to ensure continued medication safety. The RACGP acknowledges that responsibility to monitor for compliance and enforcement of Appendix M lies with State and Territory Drugs and Poisons Units and the Pharmacy Board. These two bodies need to co-operate and determine a full quality assurance program before a drug intervention is commenced.

Given the heavy retail pressures experienced in community pharmacy, an evaluation programme needs to document goals and health outcomes achieved, as well as cost to consumers. The programme logic underpinning an evaluation needs to be fully articulated and demonstrable.

The RACGP stresses the need for a clearly articulated process for measuring, monitoring and evaluating this policy at a national level. The unintended consequences of this initiative, particularly if the pharmacy has financial or commercial interests in the drugs, needs to be considered.

To facilitate audit trails, pharmacists should have Appendix M / Schedule 3 prescribing numbers to aid in detection of prescription abuse. In addition to this requirement, the RACGP recommends mandatory face-to-face assessment between a pharmacist and a patient, to mitigate internet self-dispensing or dispensing to a third party.

3.3 Compliance and enforcement

3.3.1 Compliance with general competency to supply under Appendix M

It is our view that not all pharmacies will be suitable to participate in this scheme due to the influence of industry sponsored / supported clinical services within their pharmacies. Given the challenges associated with enforcing standards and regulations regarding medicines in Australia, the RACGP recommends the following additional inclusions:

- The need for reliable statistics on adverse events for over the counter drug misuse and abuse
- Registration of pharmacies who dispense Appendix M / Schedule 3 drugs with the Therapeutic Goods Administration. As part of this process, pharmacies should be required to declare all commercial (financial and non-financial) arrangements with drug companies regarding Appendix M / Schedule 3 products
- The applicant should be required to declare relevant commercial (financial and non-financial) arrangements.

Thus, the Therapeutic Goods Administration should propose inclusion criteria to ensure that retail pharmacies safely and appropriately deliver Appendix M / Schedule 3 medication. Presently, the Therapeutic Goods Administration have provided no information about regulatory fines or consequences for non-compliance.

3.3.2 Compliance with specific Appendix M conditions for individual items, including completion of any item-specific training packages prior to supply

More detail is required on how the Therapeutic Goods Administration will monitor the impact of down-scheduling drugs on patient access and safety at a national level.

4. Proposed criteria

The RACGP provides feedback on the proposed criteria relating to the pharmacists providing patient education and health advice.

4.1 Group 1: Criteria that could be directly regulated via State and Territory legislation

Criteria 1. Specific advice by the pharmacist (patient education) is required

Patient education begins with identifying prior knowledge, which is informed by the prescriber's knowledge of that patient's individual risk profile and health literacy. This information and the privacy to talk are not available at the front counter of a pharmacy. Clinicians have explicit training in health communication that is tested as part of medical school and professional examinations. It is unclear if this important training is provided as part of pharmacy training.

Criteria 2. Specific pharmacist training on the provision of medicines

The RACGP notes that the Therapeutic Goods Administration recommends pharmacists undergo diagnostic training for some medications. Training and expertise is already available from non-pharmacist professionals trained to manage and diagnose medical conditions. The additional training of a pharmacy workforce is a duplication.

The Therapeutic Goods Administration should consider the introduction of professional standards allowing only Registered Professional staff to provide therapeutic advice within a pharmacy.

Criteria 3. Additional conditions may be imposed

The RACGP notes that additional conditions may be imposed under a general provision, on a case-by-case basis. Any additional condition should be evidence-based and subject to monitoring. Care needs to be taken that there is not a tokenistic shift of responsibility back to the GP by a pharmacist informing the GP that a new medication has been prescribed.

The responsibility for monitoring side-effects, interactions, providing follow-up and access to afterhours care typically rests with the prescriber. It is unclear if pharmacies are adequately resourced to provide this level of care. Patient records are limited for example, because patients frequently attend many different pharmacies.

The RACGP recommends the Therapeutic Goods Administration should only consider highly 'safe' Appendix M/ Schedule 3 medicines so follow up is not required. The medical conditions for which these 'safe' medicines are used should be benign and stable.

Untrained pharmacy assistants

Many pharmacies employ untrained pharmacy assistants, who may provide pseudo medical advice to patients, e.g. many complementary and alternative medicines and devices are sold on the basis of advice from pharmacy assistants. The RACGP considers this a breach of trust as patients may not be aware that they are entering an unregulated health-provider space. The Therapeutic Goods Administration should ensure that there can be no delegation of medical history-taking, patient-assessment, and patient education to pharmacy assistants.

4.2 Group 2: Criteria that could be developed into item-specific professional practice standards, which must be complied with as a condition of supply of an Appendix M good.

The RACGP opposes the suggestion that clinical decision-making be based on questionnaires, checklists, or guidelines by pharmacists in determining the appropriate supply of an Appendix M / Schedule 3 substance.

Criteria 4. Suitability of individual patient for supply of medicines containing an S3, Appendix M substance to be assessed by the pharmacist

Questionnaires and checklists fail to provide adequate safety for certain patient groups. Evidence demonstrates that patients are unaware or unable to recall about one third of their medical conditions.

This is more so when patients have language barriers or cognitive impairment. GPs use a combination of longitudinal knowledge of patients, information from specialist letters, their own electronic medical records, recent pathology results and recent physical measurements to determine whether a patient is suitable for a medication. No combination of checklist and access to My Health Record would safely replicate the level of patient-knowledge that rests with the patient's GP.

The RACGP cautions that patients who wish to access a medication against medical advice would find it easy to circumvent checklists.

As previously outlined under the conflict of interest section, prescribing within community pharmacy is driven by multiple factors, such as making money, and maintaining their customer base. In the face of these pressures, and of patient-risk, pharmacists may be less likely to say 'no' to inappropriate prescribing. Pharmacists are not properly placed to provide individual, private 10-15 minute consultations to gather all of the necessary information required for patient assessment.

The RACGP points out that medicines should only be listed as Appendix M /Schedule 3 if the safety profile of the medicines does not require detailed checklists and questionnaires.

Criteria 5. Record keeping and information sharing

The RACGP agrees that secure electronic communication is the best way to exchange information between health professionals. The My Health Record is a repository of multiple static documents. Information from the My Health Record does not flow back into a patient's electronic medical record at the GP practice. The My Health Record is not suitable as a form of communication between pharmacy and general practice.

A pharmacist who has sold an Appendix M /Schedule 3 medication to a member of the public should not transfer a duty of care for the safety of the medication to a GP. GPs should not be responsible for continuous monitoring of a patient's medication safety outside of consultations. Within a consultation, the GP will consider medication lists, interactions and potential safety concerns.

Some patients do not identify with a single practice or GP. There is currently no voluntary enrolment process in place. It is unclear how communication from a pharmacy about medicines sold to a patient will reach the GP that the patient next chooses to visit.

Criteria 6. Limitations on duration, quantity and/or frequency of supply

The RACGP re-iterates that no system has been described to monitor the impact and safety of changes to the scheduling of medications. Currently, states and territories will be able to develop different systems and rules pharmacy supply. This system-level safety monitoring requires resources that are best legislated at a national level. The system-level safety monitoring should identify societal harms rather than just individual patient harms. It should monitor overuse of medications, poor antimicrobial stewardship, near-miss patient safety events and downstream harms from fragmentation of healthcare.

The RACGP is concerned of problems that will arise if patients are able to circumvent rules around duration and quantity by visiting different pharmacies. Appendix M / Schedule 3 should have a high level of safety, not reliant on quantity and duration limitations.

Criteria 7. Need for formal diagnosis or periodic review by a medical practitioner

There must be clear documentation that the patient has indeed had a formal diagnosis. As discussed above, relying on questionnaires and patient feedback is likely to be unreliable. RACGP is also concerned that the individualised medical advice that normally would have supported prescription-only use is no longer considered necessary.

4.3 Risk of fragmentation of care

GPs use prescription frequency as a way to schedule periodic medical reviews according to individual clinical need, such as during medication titration. This individual review-frequency is lost when

medicines can be purchased directly from pharmacies as Appendix M / Schedule 3 with a one-size-fits-all review schedule. This is an example of how fragmentation of care leads to poorer care.

Furthermore, when patients are seen for inter-current illness there is an opportunity to check which medicines are overdue by prescription. This is often the first indicator that a patient has stopped taking a medication. This adherence check is lost if the patient purchases medicines directly from a pharmacist. Again, this is another example in which fragmentation of care leads to poorer care.

4.4 Reduced medication adherence and self-medication

The perceived importance of medications will be lower when patients see little difference between the purchase of optional supplements and preventive medications. For example, statins are important to prevent heart attacks and strokes in high-risk patients. If statins were available without prescription, patients might stop or change the dose without reference to their doctor. RACGP members regularly see patients stopping or starting low dose aspirin because it is available without prescription and without adequate exploration in the pharmacy.

Appendix M /Schedule 3 medicines should be free from any risk of interaction, harmful side effects and the need for monitoring. These 'safe' medications should not be treating potentially harmful medical conditions or mask symptoms of harmful medical conditions.

Medicines should only be listed as Appendix M / Schedule3 when they are not prescribed as part of a primary or secondary prevention.

It should be a mandatory requirement for face-to-face assessment between a registered health professional and patient. This will also help prevent internet self-dispensing or dispensing to a third-party.

4.5 Compensation

Consumers should be entitled to compensation for the regulatory decision that cause them harm. Consumers and doctors regularly call for health regulators to take financial accountability for their decisions.

5. Accompanying guidance for Appendix M

The RACGP is in agreement with the following aspects of the Scheduling Policy Framework (SPF):

- The substance and proposed intervention / additional requirement(s) will be listed in the Appendix
- All proposals for inclusion in Appendix M must be referred to Advisory Committee on Medicines Scheduling and undergo public consultation
- Appendix M is further explained in a note to the Scheduling Factors for Schedule 3 which states: "Additional controls over access and training for substances in Schedule 3 may be required through inclusion in Appendix M, particularly where the potential for severe and possibly irreversible injury may occur without the user being aware of exposure and/or where the pattern of the substance poses a significant risk from direct or indirect public exposure".

Final comments

The RACGP does not support monopoly of supply if the drug is safe enough that the prescriber / dispenser separation is no longer required. There may be scope to consider limited dispensing by doctors to improve patient access and reduce cost. Similarly, there is scope to consider a move away from 1-month pack sizes for low-risk ongoing medications, given the evidence of patients deferring medications because of dispensing costs.

References

¹ Schmiemann, G, Kniehl, E, Gebhardt, K et al. The Diagnosis of Urinary Tract Infection A Systematic Review. Dtsch Arztebl Int. 2010 May; 107(21): 361–367.

² Scott, G. Over the counter chloramphenicol eye drops. BMJ 2010;340:c1016

³ Steeples, L Mercieca K. Acute conjunctivitis in primary care: antibiotics and placebo associated with small increase in the proportion cured by 7 days compared with no treatment. Evid Based Med. 2012 Dec;17(6):177-8.